REMARKS:

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. §1.112, are respectfully requested in light of the remarks which follow.

I. Examiner Interviews

Applicants would like to thank the Examiner for the interviews with Applicants' representative on March 13 and October 17, 2007, regarding the present invention and proposed claim amendments that may place the application in condition for allowance. The Examiner's helpful comments and suggestions are greatly appreciated.

During the October 17, 2007 interview, the claims as amended in the response filed May 21, 2007 and new prior art identified by the Examiner was discussed. In addition, the Examiner agreed to withdraw the finality of the previous Office Action and re-open prosecution based on newly identified prior art (*see* the Office Communication dated December 5, 2007).

I. Amendments to the Claims

In the foregoing amendment, claims 1-30 have been canceled, claims 31-33 and 35 have been amended, and new claims 36-53 have been added.

Specifically, claim 31 has been amended to positively recite the function of the peptides (*e.g.* that the decapeptides inhibit the dimerization of HIV reverse transcriptase). This amendment is supported throughout the specification, for example at page 2, lines 10-17).

Claim 31 has also been further amended to recite that the antiviral peptide "consists of" the recited decapeptide. The transitional phrase "consisting of," when it appears in a clause in the body of a claim, excludes any element not specified in that clause. Accordingly, this amendment distinguishes the claimed invention from any inhibitors of HIV replication wherein the antiviral peptide is greater than ten amino acids long. However, Applicants would like to emphasize that the term "consisting of" does not exclude other elements from the claim as a whole. Thus, the inhibitor of HIV replication recited in claim 31 encompasses additional elements, such as an MPG peptidyl carrier. (*See, e.g.,* MPEP § 2111.03.)

In addition, claim 31 has been amended to recite that the antiviral peptide "is not KETWETWWTE." As noted in MPEP § 2173(i), "[a]ny negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims" (citing *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) and *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984)). The KETWETWWTE peptide is explicitly disclosed in Table I of the present specification. Thus, this amendment complies with the written description requirement under 35 U.S.C. § 112, first paragraph, and does not comprise "new matter."

Claim 31 has also been further amended by deleting the term "analog" from the claim.

Other amendments have been made to claim 31 in order to clarify the claim language. Clarifying amendments have also been made to claims 32 and 33. These amendments are merely editorial in nature and are not intended to change the scope of the claims or of any of the elements recited therein.

Claim 35 has been amended by deleting the phrase "pharmaceutical composition" from the preamble, and to recite that the inventive composition "further comprises one or more pharmaceutically acceptable excipients," as supported generally in the present specification at page 8, line 22 to page 9, line 5.

New claims 36-53 have been added.

Claims 36-44 depend ultimately from claim 35 and recite particular embodiments of the invention recited in claim 35. Support for claims 36-44 can be found throughout the specification and original claims as filed.

In particular, claims 41 and 42 recite inhibitors wherein the MPG peptidyl carrier and the antiviral peptide are in the form of a complex, and wherein the complex comprises the MPG peptidyl carrier and the antiviral peptide at a ratio of about 20 molecules of the MPG peptidyl carrier for 1 molecule of the antiviral peptide. Claims 41-42 are supported at least at page 24945 of Morris et al., JBC 274:24941-24946, incorporated herein by reference at page 13, line 7 of the specification.

Claims 45-53 are directed to inhibitors of HIV replication that comprise a chimeric peptide. In particular, claim 45 recites a chimeric peptide "comprising" a decapeptide and an MPG carrier peptide. Claims 45-53 are supported throughout the specification and original claims as filed (*see, e.g.*, page 6, lines 31-33 and Example 6 at pages 18 and 19). Applicants

note that full-length HIV reverse transcriptase does not include an MPG carrier peptide. Accordingly, the chimeric peptides disclosed in the specification and recited in the present claims are not taught or suggested by any reference that may disclose full-length HIV reverse transcriptase.

The amendments to the claims, including cancellation of claims, have been made without prejudice or disclaimer to any subject matter recited or canceled herein. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments of the above-identified application are respectfully requested.

II. Response to Claim Rejections Under 35 U.S.C. § 112, First Paragraph

At pages 1-5 of the Office Action, claims 1-10, 18, and 31-35 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to meet the written description requirement. This rejection is respectfully traversed, for at least the following reasons.

Initially, Applicants note that to expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, the claims have been amended as described above.

Further, Applicants submit that the pending claims are sufficiently described. First, as discussed in the interview, Examples 2 and 3 of the present specification show that p7 inhibits replication in several HIV isolates, and not just in HIV-1 BH10. Second, the ability of p7 to inhibit replication in a variety of HIV-1 and HIV-2 isolates implies that all of the peptides shown in Table I are likely to possess the desired antiviral activity. Third, the HIV-RT crystal structure has been determined and analyzed, as disclosed in the specification and in references cited therein (*see, e.g.*, page 1, line 30 to page 2, line 2). Thus, a representative number of peptides are disclosed in the specification.

In the March 13, 2007 interview, the Examiner agreed that the specification discloses sufficient information regarding the structure of the peptides recited in claims 31-35, and provides a correlation between the recited consensus sequence and antiviral function. The Examiner then indicated that the outstanding written description rejection would likely be withdrawn as to all pending claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

III. Additional Remarks in Response to Examiner Interviews

A. 35 U.S.C. § 112, First Paragraph

Applicants note that during the March 13, 2007 interview, the Examiner indicated that claims 31-35 (directed to a decapeptide containing "a basic amino acid in position 1, an acidic amino acid in positions 2 and 5, and a tryptophan in positions 4, 7, and 8 wherein the amino acid at position 3 is threonine, isoleucine or valine; the amino acid at position 6 is threonine, alanine, and glutamine; the amino acid at position 9 is threonine, alanine, valine, isoleucine, methionine, or aspartate; and the amino acid at position 10 is glutamate, aspartate or asparagine (claim 31)) appear to be sufficiently enabled. In this regard, the Examiner noted that in light of the information regarding conserved residues at the RT dimerization interface, and the replication inhibition results set forth in the specification, the peptides recited in claims 31-35 could reasonably be expected to possess the desired antiviral activity.

However, the Examiner also pointed out that claim 35 recited "pharmaceutical compositions" comprising the inhibitor of the present invention. According to the Examiner, due to the unpredictability in the art of HIV therapy, a person of ordinary skill in the art would not be able to use the recited "pharmaceutical composition" to treat a disease or condition without undue experimentation. To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, as noted above claim 35 has been amended to recite that the inventive composition "further comprises one or more pharmaceutically acceptable excipients," as suggested by the Examiner.

Accordingly, Applicants respectfully submit that a person of ordinary skill in the art could make and use the presently claimed invention without undue experimentation.

B. Prior Art

During the October 17, 2007 interview, the Examiner stated that the claims presented in the response filed May 21, 2007 (not entered; *see* Advisory Action dated September 13, 2007 in the present application) do not appear to be patentable over two newly-identified prior art references (van der Burg et al., J. Immunol. 159:3648-3654 (1997) and Morris et al., JBC 274:24941-24946 (1999)).

In particular, the Examiner indicated that van der Burg et al. discloses the peptide KETWETWWTE. According to the Examiner, the reference peptide is encompassed by the

consensus sequence recited in present claim 31, and would inherently inhibit the dimerization of HIV reverse transcriptase.

As noted above, claim 31 has been amended herein to recite that the antiviral peptide "is not KETWETWWTE." Since each and every element of Applicant's claimed invention is not taught, either explicitly or inherently, by van der Burg et al., such reference fails to anticipate the claims of the present application.

The Examiner also stated that Morris et al. describes the peptides recited in the present claims.

In response, Applicants submit herewith a Declaration Under 37 C.F.R. § 1.132 establishing that Morris et al. describes the present inventors' own work. In particular, the named inventors of the present application are co-authors of Morris et al., along with additional co-author Laurent Chaloin. As stated in the Declaration, the named inventors are the only inventors of the invention claimed in the present application and described in Morris et al., and the additional co-author of the reference was merely working under the direction and supervision of one of the named inventors. Accordingly, Morris et al. does not qualify as prior art under § 102(a) against the present application.

C. Claims 45-53

During the October 17, 2007 interview, the Examiner indicated that new claims 45-53, directed to chimeric peptides comprising an antiviral decapeptide and an MPG peptidyl carrier peptide, appear to be allowable. Applicants thank the Examiner for his consideration of these claims.

CONCLUSION

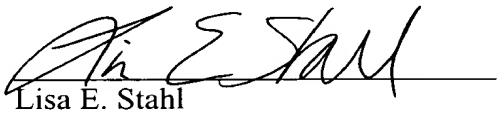
In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited. In the event that there are any questions relating to this Supplemental Amendment and Reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: December 19, 2007

By: 
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